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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Barbara Roniker, et al.	Atty. Docket No.: 1-51765.00002
Confirmation No. 6230	
Application No.: 09/402,634	Group Art Unit: 1614
Filed: March 27, 2000	Examiner: Donna A. Jagoe
For: METHOD OF USING CYCLOOXYGENASE-2 INHIBITORS IN THE PREVENTION OF CARDIOVASCULAR DISORDERS	

REPLY BRIEF

This Reply Brief is filed to address certain points raised in the Examiner's Answer (Answer). Appellants believe this brief is timely filed. However, if an extension of time is needed, and/or if a fee needs to be paid to enter and consider the Reply Brief, please charge the necessary fee to our Deposit Account No. 19-0733.

Argument

Though acknowledging that the pending rejection is based on a hindsight reconstruction of the prior art (Answer page 12), the Answer argues that such a reconstruction is permissible "so long as it takes into account only knowledge which was within the level of ordinary skill at the time the invention was made, **and does not include knowledge gleaned only from applicant's disclosure.**" (Emphasis added).

In seeking to justify the obviousness rejection, however, the Answer ignores its own caveat. In particular, the Answer refers to applicant's disclosure, stating: "[i]n response, **the examiner turns to the instant specification** to shed light on the nature if [sic] the instant invention." (Answer page 12, lines 14-15; Emphasis added).

The Answer does exactly what the cited case law forbids – it impermissibly refers to applicants’ own specification in an effort to support the tendered obviousness rejection.

All of the appealed claims are directed to a method for the **prophylactic treatment** of a subject at risk of developing a specific set of cardiovascular disorders.¹ The Answer effectively ignores the claimed limitation to **prophylactic treatment** in presenting its support for the obviousness rejection. Instead, the Answer fixates on an unclaimed aspect of the pending application, related to the treatment of inflammation directly. See for example the sentence bridging pages 13 and 14 of the Answer:

In this case, since it is known that anti-inflammatories such as COX-2 inhibitors treat inflammation related **vascular disease** and **myocardial infarction** and since it is known from the teaching of “Merck” that lipid lowering agents reduce the formation of plaque on blood vessels which would lead to the inflammation related vascular disease of the Searle WO Publication, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine these two agents to treat a vascular disease such as atherosclerosis (a vascular disease).

That treatment is NOT embraced by the claims.

In this regard, the Answer specifically argues that “[i]f there is a pathway other than the treatment of inflammation, used to treat the instantly claimed cardiovascular

¹ The prophylactic treatment requirement is recited in different ways throughout the claims as “a method for reducing risk of...,” “a method for reducing risk of an onset of...,” “a method for treating a subject at risk of developing a...” All claims refer to a prophylactic treatment, rather than the direct treatment of the disease state itself.

disorders, it is not described in appellants' specification." The short response is that appellants are not claiming a method of treating inflammation directly or a method of treating a cardiovascular disorder directly. Again, the claims are to a **prophylactic treatment**. By failing to recognize this distinction, the Answer assumes there is a logical nexus for the combination of the two cited references, when one simply does not exist for rejecting the pending claims.

The fundamental premise of the obviousness rejection is that the separately cited references purportedly suggest using different drugs for the same purpose. That also is NOT the case. Neither of the cited references suggests using the described drugs for the claimed prophylactic treatment. Nor does the Answer cite to a specific point in either reference where there is the required common disclosure.

As appellants' main brief demonstrates, the primary reference (the Searle PCT), at most, describes using selective COX-2 inhibitors for treating inflammation directly. The secondary reference (Merck) describes using statins (HMG-CoA reductase inhibitors) for treating patients having an elevated level of low density lipoproteins (LDL). These disclosed uses simply are NOT the "same purpose." Furthermore, there is nothing in the Searle PCT suggesting that the COX-2 inhibitors would have any utility for the purpose described in the Merck reference and vice versa.

The Answer attempts to skirt these differences by arguing that the features that are missing from each of the separate references are not recited in the claims (Answer page 14). The Answer, however, misses the point. The inadequacies noted in the cited references goes to the heart of the appropriateness of using them in combination to frame

the rejection. Because the targets of the drugs in the separate references are so different a skilled worker would not have found it obvious to combine their teachings.

In its misplaced attempt to support the stated premise, the Answer also over-generalizes the disparate teachings of these references and slants the exact nature of what the references teach. In the Answer (page 13), it is asserted that the same purpose for using the drugs of the two cited references is "to treat/prevent vascular diseases e.g. atherosclerosis." The Searle PCT only indicates that the disclosed compounds are useful "in treating **inflammation** in such disease as vascular diseases [and] ... myocardial ischemia." The word "prevent" is supplied solely by the Examiner, nowhere in the Searle PCT is there any hint of using the described drugs in a prophylactic method.

For the reasons given above and in appellants' main brief², the rejection of claims 13, 15-17, 19-24, 26-31, 40-43, 45-52, 54-62 and 64-68 under 35 U.S.C. § 103(a) is improper. The Board of Patent Appeals and Interferences should reverse the rejection.

Respectfully submitted,

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² In this regard, appellants note that the Answer chooses to ignore the issuance of U.S. 6,245,797 and its value as evidence of the patentability of the pending claims, stating that "each patent application is examined on its own merits ..."